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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

27752 7590 06/16/2006

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EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

Receipt of amendment, RCE and remarks all dated 4-12-06 is acknowledged.

Claims 36, 38, 41-44, 46 and 48 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-12-06 has been entered.

The following new rejection is applied to the instant pending claims:

#### ***Claim Rejections - 35 USC § 103***

Claims 36, 38, 41-44, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,112,604 ('604) by itself.

'604 teaches oral, aqueous suspension formulations comprising a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components (col. 1, lines 40-57 and tables 1 and 2). With respect to the drug, '604 teach addition of anti-tussive, anti-inflammatory, bronchodilator etc (col. 3, lines 47-56), similar to those claimed in the instant. '604 teach the same amount of citric acid that falls within the instant claimed range (tables). With respect to the size and the amount of colloidal silicon particles claimed, instant claims 36 and 43 recite a range of

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2% to 50% by weight of the composition. '604 teach upto 2% of colloidal silicon dioxide and thus meet the claimed percentage. Further, while '604 does not mention the particle size, the reference teaches "colloidal" silicon dioxide which by definition has a particle size in the range of nanometers (admitted on page 4, lines 29-36 of instant specification). Thus, absent evidence to the contrary, the particle size of the colloidal silicon dioxide of '604 meets the claimed range. '604 teach oral suspension that read on the claimed method of administering a medicament by swallowing the composition. '604 fail to specify the amount of water in the composition. However, both the examples of '604 recite ingredients that include water in the simple syrup preparation (col. 6, lines 14-20 and claim 1). Accordingly, absent unexpected advantage with the claimed high amounts of water, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include the appropriate amount of water to prepare an oral aqueous liquid composition comprising the claimed active agent, silicon dioxide and citric acid, without losing the therapeutic efficiency of the drug as well as the stability afforded by silicon dioxide. With respect to the amount of silicon dioxide of instant claims 38 and 44, '604 teach upto 2% and not the claimed percentage. However, instant claims recite a wide range of 2% to 50% that includes very low and very high amounts, suggesting that the amount of silicon dioxide is not critical. Instant invention also fails to define what the term "about" stands for or what standard deviation constitutes "about 2%" or "about 3%". Accordingly, in the absence of any unexpected advantage, one of an ordinary skill in the art would have been motivated to optimize the amount of silicon dioxide in the composition of '604 because '604 suggest that colloidal

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silicon dioxide imparts stability to the suspension so as to remain stable in suspension for a long time.

***Claim Rejections - 35 USC § 112***

Claims 36, 38, 41-44, 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 43 recite the term “less than about”, which is indefinite because while the term “about” allows for some flexibility with regards to the particle size, the term “less than” with respect to the “about” does not clearly state what the lower limit of the particle size is and what deviation that lower limit allows for. A clarification and correction is requested.

***Response to Arguments***

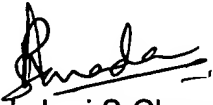
Applicant's arguments with respect to claims 36, 38, 41-44, 46 and 48 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
June 13, 2006